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TITLE: Nutritional supplements for aged pets

### Abstract Paragraph (1):

Disclosed herein are compositions to meet the needs of aged pets and other animals. Pet foods, pet treats and pet supplements with anti-aging effects are disclosed whose compositions include the R-.alpha.-lipoic acid in the amount of 0.10 grams to 1.5 grams and L-carnitine in the amount of 0.10 grams to 3 grams in addition to the usual composition. Optionally, coenzyme Q can be added in an amount of at least 1 mg/day. Optionally, creatine can be added in an amount of at least 0.2 grams/day. These additional components fight age-related declines in mitochondrial function, which result in less energy and other signs of aging.

#### Summary of Invention Paragraph (2):

[0002] The present invention is generally directed to <u>pet food</u> and dietary supplements. More specifically, the present invention relates to the addition of the combination of lipoic acid and carnitine to these compositions. Optional additional ingredients are coenzyme Q and creatine.

### Summary of Invention Paragraph (4):

[0003] Many pet foods contain nutrition for a specific stage of the pet's life. Stages of a pet's life are broken down as follows: kitten or puppy is up to 1 year, adult cat or dog is one to six years, and a senior cat or dog is over six years old. However, different animals age at different rates. Cats are often considered older or senior, at seven to eight years of age and geriatric or very old at 10 to 12 years. Dogs often are considered older between 7.5 and 13.5 years of age. Dogs often are considered older when they reach half of their life expectancy, which corresponds to about five years for larger dogs and seven years for smaller dogs.

#### Summary of Invention Paragraph (7):

[0006] The goals of <u>pet\_foods</u> for older animals have been stated as maintaining optimal nutrition, managing risk factors, managing diseases, and improving quality and longevity of life. So far, that has meant reducing <u>protein</u>, <u>fat</u>, energy sources, phosphorus and sodium and increasing water and <u>fiber</u>. However, very old dogs (greater than 12 years) may require somewhat more fat and energy sources.

#### Summary of Invention Paragraph (8):

[0007] An example of a formulation for older dogs is the Science Diet.RTM. Canine Senior.RTM. product that provides fewer calories, more <u>fiber</u> and lower phosphorus. The dry formula has 350 kcal/cup. It has the following nutrient contents per 100 kcal: <u>protein 4.8 g, fat 2.8 g, carbohydrate 16.5 g, crude fiber 0.8 g, calcium 155 mg, phosphorus 144 mg, sodium 45 mg, potassium 163 mg, chloride 141 mg and magnesium 30 mg. It also contains the following vitamins: choline chloride, vitamin A, vitamin D3, vitamin E, niacin, thiamine, calcium pantothenate, pyridoxine hydrochloride, riboflavin, folic acid, biotin and vitamin B12.</u>

#### Summary of Invention Paragraph (9):

[0008] A canned turkey Canine Senior.RTM. formula provides about 393 kcal per 418-gram can. It has the following nutrient contents per 100 kcal: protein 4.9 g, fat 3.2 g, carbohydrate 15.8 g, crude fiber 0.5 g, calcium 159 mg, phosphorus 138 mg, sodium 43 mg, potassium 181 mg, chloride 149 mg and magnesium 23 mg. It also contains the following vitamins: D-activated animal sterol, vitamin E, niacin, thiamine, calcium

pantothenate, pyridoxine hydrochloride, riboflavin, folic acid, biotin and vitamin B12.

# Summary of Invention Paragraph (10):

[0009] The Science Diet Feline Senior.TM. canned fish formula offers lower energy and higher fiber than pet food for younger cats. It provides 150 kcal per 156-gram can. It has the following nutrient contents per 100 kcal: protein 9.5 g, fat 5.8 g, carbohydrate 5.3 g, crude fiber 1.1 g, calcium 219 mg, phosphorus 177 mg, sodium 115 mg, potassium 198 mg, chloride 177 mg, magnesium 17 mg, and taurine 146 mg. It also contains the following vitamins: vitamin A, D-activated animal sterol, vitamin E, niacin, thiamine, calcium pantothenate, pyridoxine hydrochloride, riboflavin, folic acid, biotin and vitamin B12.

#### Summary of Invention Paragraph (12):

[0011] Carnitine and carnitine derivatives have been used as metabolites in animal husbandry and for human diet and therapy. U.S. Pat. No. 5,362,753 (Method of increasing the hatchability of eggs by feeding hens carnitine); U.S. Pat. No. 4,687,782 (Nutritional composition for enhancing skeletal muscle adaptation to exercise training); U.S. Pat. No. 5,030,458 (Method for preventing diet-induced carnitine deficiency in domesticated dogs and cats); U.S. Pat. No. 5,030,657 (L-carnitine supplemented catfish diet); U.S. Pat. No. 4,343,816 (Pharmaceutical composition comprising an acyl-carnitine, for treating peripheral vascular diseases); U.S. Pat. No. 5,560,928 (Nutritional and/or dietary composition and method of using the same); U.S. Pat. No. 5,504,072 (Enteral nutritional composition having balanced amino acid profile); U.S. Pat. No. 5,391,550 (Compositions of matter and methods for increasing intracellular ATP levels and physical performance levels and for increasing the rate of wound repair); U.S. Pat. No. 5,240,961 (Method of treating reduced insulin-like growth factor and bone loss associated with aging); etc.

# Summary of Invention Paragraph (16):

[0015] What is needed is an improved nutritional <u>pet food</u> which truly is formulated to meet the needs of older pets. A survey of <u>pet food</u> Web sites uncovered no formula providing carnitine or lipoic acid. Such a <u>pet food</u> would also provide the latest in anti-aging compounds that have been shown to increase energy and stamina, with fewer calories.

#### Summary of Invention Paragraph (23):

[0020] Pet foods lack four important ingredients: carnitine, lipoic acid, coenzyme Q and creatine. These constituents are essential to discourage aging and provide more energy to older animals and others with unhealthy mitochondria. Recent research has shown precisely how these compounds work to promote healthy mitochondria, which are the energy powerhouses of the cells. Mitochondria are responsible for the production of ATP and are present in relatively high numbers in essentially all cells of the body. The mitochondrial electron transport system consumes approximately 85% of the oxygen utilized by a cell. Cellular energy deficits caused by declines in mitochondrial function can impair normal cellular activities and compromise the cell's ability to adapt to various physiological stresses, a major factor in aging. Because of this high oxygen use, the mitochondria also have the highest production of oxidants.

# Summary of Invention Paragraph (24):

[0021] Oxidants damage mitochondria in three important ways. Oxidants damage DNA, lipids and protein. The intra-mitochondrial DNA (mtDNA) have levels of oxidative damage which are at least 10-fold higher than those of nuclear DNA, which correlates with the 17-fold higher evolutionary mutation rate in mtDNA compared with nuclear DNA. mtDNA oxidation accumulates as a function of age, which has been shown in several species, including humans. This may lead to dysfunctional mitochondria. Mitochondrial protein damage is also age-related and may decrease energy production and increase oxidant production. Oxidative damage to mitochondrial lipids contributes to the decreasing fluidity of cell membranes with age. The lipid cardiolipin is a major component of the mitochondrial membrane and facilitates the activities of key mitochondrial inner membrane enzymes. The aged, damaged mitochondrial membrane cannot contain the oxidants, nor can it maintain as high a polarity as the younger membrane.

## Summary of Invention Paragraph (25):

[0022] Fatty acid oxidation is an important energy source for many tissues. The activity of carnitine-acetyl-carnitine exchange across the inner mitochondrial membrane is of great importance. The activity of this exchange reaction is decreased significantly with age, which may be due to a lower intra-mitochondrial pool of carnitine. L-carnitine or acyl-L-carnitine (ALC) has been shown to slow or reverse this age-related dysfunction. It also can reverse the age-related decrease in cardiolipin, age-associated decrease in mtDNA transcription, and decreased membrane potential. By itself, L-carnitine or ALC cannot correct the problem of excess oxidants. In fact, it was recently reported that carnitine supplementation increased oxidant production by 30% and decreased cell antioxidants markedly. Thus, ALC administration in older individuals may contribute to greater oxidative stress.

#### Summary of Invention Paragraph (28):

[0025] Carnitine is available in many forms and all those are included in the invention of the combination of carnitine and thioctic acid. Carnitine and carnitine derivatives have been used as metabolites in animal husbandry and for human diet and therapy. U.S. Pat. No. 5,362,753 (Method of increasing the hatchability of eggs by feeding hens carnitine); U.S. Pat. No. 4,687,782 (Nutritional composition for enhancing skeletal muscle adaptation to exercise training); U.S. Pat. No. 5,030,458 (Method for preventing diet-induced carnitine deficiency in domesticated dogs and cats); U.S. Pat. No. 5,030,657 (L-carniting supplemented catfish diet); U.S. Pat. No. 4,343,816 (Pharmaceutical composition comprising an acyl-carnitine, for treating peripheral vascular diseases); U.S. Pat. No. 5,560,928 (Nutritional and/or dietary composition and method of using the same); U.S. Pat. No. 5,504,072 (Enteral nutritional composition having balanced amino acid profile); U.S. Pat. No. 5,391,550 (Compositions of matter and methods for increasing intracellular ATP levels and physical performance levels and for increasing the rate of wound repair); U.S. Pat. No. 5,240,961 (Method of treating reduced insulin-like growth factor and bone loss associated with aging); etc. Most preferably, the carnitine is acetyl-L-carnitine.

# Summary of Invention Paragraph (37):

[0034] In addition to the compositions mentioned above and the examples given below, animal snacks, "treats", and supplements also benefit from the addition of a carnitine and a form of thioctic acid. The carnitine, thioctic acid, and optionally coenzyme Q and/or creatine can be added to bulk powders or dried or canned pet food. The combination of carnitine, thioctic acid, and optionally coenzyme Q and/or creatine can be mixed with any cooked or uncooked food.

# Detail Description Paragraph (2):

[0043] The Eukanuba Senior Maintenance (IAMS) is formulated to help nutritionally stabilize the senior dog's digestive system and support a healthy intestinal environment with fiber from beet pulp and fructo-oligosaccharides. The Eukanuba Senior Maintenance also has increased levels of antioxidants to help maintain the immune system in senior dogs. The senior maintenance diet was formulated with 50% more antioxidants than their Adult Formulas, from sources such as vitamin E and Beta-Carotene, which is believed to help maintain the immune system of the senior dog. This is intended for small breeds over 8 years of age, medium breeds over 7 years of age, large breeds over 6 years of age, and giant breeds over 5 years of age. Its ingredients include chicken by-product meal, corn meal, ground grain sorghum, ground whole grain barley, chicken, fish meal, dried beet pulp (sugar removed), chicken fat (preserved with mixed tocopherols, a source of vitamin E, and citric acid), dried egg product, brewers dried yeast, vitamins and minerals. It provides 4,219 kcal/kg or 350 kcal/cup in the following distribution: protein 27%, fat 28%, and carbohydrate 45%.

### Detail Description Paragraph (3):

[0044] To improve the nutritional value for senior dogs, at least 0.1 grams of R-.alpha.-lipoic acid, at least 0.1 grams of <u>L-carnitine</u>, and optionally at least 1 mg of Q10 and/or at least 0.2 grams of creatine must be added daily.

### Detail Description Paragraph (5):

[0045] The lams Senior Formula for Cats meets most of the special nutritional needs of cats over 7 years of age. As a cat ages, he can benefit from highly digestible premium nutrition more than ever. Iams Senior Formula provides essential protein levels to help maintain muscle mass and mobility. And with 30% less fat than Iams Original Formula, the cat has energy to stay active without excess fat for weight gain. The key

ingredient of the Iams Senior Cat Food is chicken <u>protein</u> to maintain muscle tone, body systems, skin, and coat. Ingredients include chicken by-product meal, chicken, rice flour, corn meal, dried beet pulp (sugar removed), dried egg product, natural chicken flavor, fish meal, potassium chloride, brewers dried yeast, dl-methionine, calcium carbonate, salt, choline chloride, vitamin E supplement, zinc oxide, chicken fat (preserved with mixed tocopherols, a source of vitamin E, and citric acid), vitamins and minerals. This formulation provides 4,108 kcal/kg, or 373 kcal/cup from the following sources: protein 32%, fat 34%, and carbohydrate 34%.

# Detail Description Paragraph (6):

[0046] To properly supply nutrients to older cats, we supplement the above formula with at least 0.1 grams of R-.alpha.-lipoic acid, at least 0.1 grams of L-carnitine, and optionally at lest about 1 mg of Q10 and/or at least 0.2 grams daily, depending on weight.

# <u>Detail Description Paragraph</u> (8):

[0047] Kasco.RTM. Lite Dog Food is a low-protein, low-fat, low-calorie formula for maintenance for less active and older dogs. It contains the following ingredients: ground yellow corn, wheat middlings, poultry by-product meal, meat and bone meal, ground wheat, beet pulp, poultry <a href="fat">fat</a> (preserved with mixed tocopherols), dicalcium phosphate, poultry digest, salt, calcium carbonate, brewers dried yeast, choline chloride, zinc proteinate, vitamin E supplement, ascorbic acid, zinc oxide, manganese proteinate, copper proteinate, extract of rosemary, manganous oxide, cooper sulfate, vitamin A acetate, niacin supplement, calcium pantothenate, vitamin B12, vitamin D3, pyridoxine hydrochloride, riboflavin, thiamin mononitrate, calcium iodate, biotin, sodium selenite, and folic acid. Kasco Lite has 322 kcal per standard cup. Its guaranteed analysis is crude <a href="protein">protein</a> (min) 18%, crude <a href="fat">fat</a> (min) 6%, crude <a href="fiber">fiber</a> (max) 5%, and moisture (max) 11%.

#### Detail Description Paragraph (9):

[0048] To formulate this product specifically for older dogs, we supplement the above formula with at least 0.1 grams of R-.alpha.-lipoic acid, at least 0.1 grams of L-carnitine, and optionally at least about 1 mg of Q10 and/or at least 0.2 grams of creatine per day.

# Detail Description Paragraph (11):

[0049] Heinz provides a blend of ingredients called the Custom Fitness.TM. formula of Cycle Senior. It contains rice and oatmeal that eases digestion for the sensitive systems of older dogs. Other specifications include anti-oxidant vitamins A, C, and E plus beta carotene, for a strong immune system and clear vision; and no added salt; and limited calcium, phosphorus, and <a href="fat">fat</a>. Ingredients of the dry formula include corn, soybean hulls, chicken by-product meal, feeding oat meal, brewers rice, whole wheat, animal <a href="fat">fat</a> (BHA used as a preservative), animal digest, condensed grain fermentation solubles, bone phosphate, calcium carbonate, potassium chloride, L-lysine hydrochloride, L-threonine, D,L-methionine, choline chloride, minerals (ferrous sulfate, zinc oxide, manganous oxide, copper sulfate, calcium iodate, sodium selenite), vitamins (vitamin E supplement, niacin, D-calcium pantothenate, riboflavin supplement, pyridoxine hydrochloride, thiamin mononitrate, vitamin A supplement, folic acid, biotin, vitamin B12 supplement, vitamin D3 supplement), antioxidant blend (ascorbic acid, beta carotene, marigold extract), BHA (preservative), tocopherols (preservative), citric acid (preservative), rosemary extract (preservative).

# Detail Description Paragraph (13):

[0051] To convert these products to support the metabolism of active seniors, the following formulation additions are made: at least 0.1 grams of R-.alpha.-lipoic acid, at least 0.1 grams of L-carnitine, and optionally at least 1 mg of Q10 and/or at least 0.2 grams of creatine per day.

# Detail Description Paragraph (15):

[0052] Mera Dog Sensitive is a well-tolerated maintenance formula that is suitable for the senior and less active dog. Main ingredients are turkey and rice, which are highly digestible and provide protein with reduced calories. Specifically, ingredients include rice (60%), turkey meat meal (20%), poultry <a href="fat.">fat.</a>, beet <a href="fiber">fiber</a>, linseed</a>, brewers yeast, minerals, poultry meat hydrolysate, DL-methionine, L-lysine. Additives include vitamin A 15,000 I. E./kg, vitamin D3 1.500 I. E./kg, vitamin E 120 mg/kg, and copper

19 mg/kg. Guaranteed Analysis is crude protein 21.0%, crude fat 9.0%, crude fiber 2.5%, crude ash 7.0 %, calcium 1.2%, phosphorus 1.0%, and sodium 0.4%.

### Detail Description Paragraph (16):

[0053] To convert this product to support the metabolism of active seniors, the following formulation additions are made: at least 0.1 grams of R-.alpha.-lipoic acid, at least 0.1 grams of L-carnitine, and optionally at least 1 mg of Q10 and/or at least 0.2 grams of creatine per day.

# Detail Description Paragraph (19):

[0055] To convert this product to support the metabolism of active seniors, the following formula additions are made: at least 0.1 grams of R-.alpha.-lipoic acid, at least 0.1 grams of L-carnitine, and optionally at least 1 mg of Q10 and/or at least 0.2 grams of creatine per day.

### Detail Description Paragraph (21):

[0056] The Science Diet Canine Senior product described in the Background can benefit from supplementation with at least 0.1 grams of R-.alpha.-lipoic acid, at least 0.1 grams of L-carnitine, and optionally at least 1 mg of Q10 and/or at least 0.2 grams of creatine per day.

# Detail Description Paragraph (23):

[0057] The Canine Senior formula described in the Background can benefit from supplementation with at least 0.1 grams of R-.alpha.-lipoic acid, at least 0.1 grams of L-carnitine, and optionally at least 1 mg of Q10 and/or at least 0.2 grams of creatine per day.

## Detail Description Paragraph (25):

[0058] The Science Diet Feline Senior canned fish formula (as well as other Science Diet cat foods) can benefit from supplementation with at least 0.1 grams of R-.alpha.-lipoic acid, at least 0.1 grams of L-carnitine, and optionally at least 1 mg of Q10 and/or at least 0.2 grams of creatine per day.

## Detail Description Table CWU (1):

1 Guaranteed Analysis: Nutrient (percent) Crude Protein min. 26.0% Crude Fat min. 10.0% Crude Fiber max. 4.0% Moisture max. 10.0% Omega- 6 Fatty Acids min. 1.75% Omega-3 Fatty Acids min. 0.25%

## Detail Description Table CWU (2):

2 Guaranteed Analysis: Nutrient (percent) Crude Protein min 32.0% Crude Fat min 14.0% Crude Fat max 16.5% Crude Fiber max 3.0% Moisture max 10.0% Ash max 6.75% Magnesium max 0.099% Taurine min 0.15% Vitamin E not less than 200 IU/kg

## Detail Description Table CWU (3):

3 Dry Formula Guaranteed Analysis As Fed Dry Weight Protein 19.50% 21.31% Sodium 0.08% 0.09% Crude Fat Not less than 9.00% Crude Fiber Not more than 4.00% Moisture Not more than 12.00% Calcium Not less than 0.60% Phosphorous Not less than 0.50% Sodium Not more than 0.15% Calories per cup 350 Calories

# Detail Description Table CWU (4):

4 Canned Formula Guaranteed Analysis As Fed Dry Weight Protein 5.13% 26.50% Sodium 0.15% 0.77% Crude Fat Not less than 3.0% Crude Fiber Not more than 5.0% Moisture Not more than 82.0% Calories per cup 288 Calories

#### CLAIMS:

- 1. A pet food with anti-aging properties, the food comprising a) an effective amount of a suitable antioxidant; b) an effective amount of a carnitine; c) carbohydrate; d) protein; e) fat; and e) fiber.
- 2. The pet food of claim 1 wherein the carnitine is ALC and the effective amount is about 0.1 grams to 3 grams.
- 3. The pet food of claim 1 in which the antioxidant is R-.alpha.-lipoic acid in the amount of 0.1 grams to 1.5 grams.

- 4. The pet food of claim 1, further comprising coenzyme Q in the amount of at least about 1 mg/day.
- 5. The pet food of claim 1, further comprising creatine in the amount of at least about 0.2 grams/day.
- 6. A <u>pet treat</u> with anti-aging properties, the treat comprising a) an effective amount of a suitable antioxidant; b) an effective amount of a carnitine; c) at least one energy source; and d) flavors.
- 7. The <u>pet treat</u> of claim 6 wherein the carnitine is ALC and the effective amount is about 0.1 grams to 3 grams.
- 8. The pet treat of claim 6 in which the antioxidant is R-.alpha.-lipoic acid in the amount of about 0.1 grams to 1.5 grams.
- 9. The <u>pet treat</u> of claim 6, further comprising coenzyme Q in the amount of at least about 1 mg/day.
- 10. The pet treat of claim 6, further comprising creatine in the amount of at least about 0.2 grams/day.